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09/898,292	07/03/2001	Michele Amouyal	1231-01	2241

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EXAMINER

SIEW, JEFFREY

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,292

Applicant(s)

AMOUYAL, MICHELE

Examiner

Jeffrey Siew

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 14 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 11-26 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-23 is/are rejected.
- 7) ☒ Claim(s) 11-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 14 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 15.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. The previous restriction filed 7/9/02 is withdrawn. Due to office oversight, the preliminary amendment filed 10/10/01 was not entered. The following restriction follows in light of the entered preliminary amendment.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 11-23, drawn to method of circularizing recombinant vector, classified in class 435 , subclass 6.
 - II. Claims 24-26, drawn to kit containing ligase and compaction agent such as histones classified in class 435, subclass 6.
3. The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the kit contains reagents that may be used to perform other DNA processes such as Ligase chain reaction and histones are involved mitosis of chromosomes and not solely for circularizing recombinant vectors.

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Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Mr. T. Daniel Christenbury on 11/3/02 a provisional election was made without traverse to prosecute the invention of Group I, claims 11-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. The request for corrected filing receipt filed 7/1/02 is acknowledged. The docket clerk shall review and correct accordingly. The drawings filed 1/14/02 are approved by the examiner and the draftsman. The corrected filing receipt filed 1/22/02 is acknowledged and corrected.

Claim Objections

5. Claims 11-23 are objected to because the phrase process. It is preferred in US practice that the term "method" be used.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 15, 20, 21 & 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 14, 15 & 23 are indefinite because it is unclear the extent of the scope encompassed by the term "protein derivative".

B) Claims 20 & 21 are indefinite. It is unclear whether the X values define a the amount of DNA compact agent to be used. Moreover, as the variables of ng DNA and bp are unlimited, any concentration of DNA compacting agent may be expressed by the formula; it is unclear as to what the concentration formula imparts onto the method. A

C) Claim 13 is confusing. It is unclear as to what the term "cellular medium". It is unclear as to whether the steps details a transfection step into a cell or simply putting into a physiological equivalent buffer.

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Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11,14-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sobczak et al (Eur. J. Biochem. Vol. 175 pp. 379-385 1988).

Sobczak et al teach preparing circular pBR322 vector with ligated EcoRI or HincII inserts and compaction agent histone H1 (see whole doc. esp. abstract and page 379). The H1 was added to the mixture (see ligase assay). They also teach histone is added prior to ligase (see figure 5). They also teach addition of 4 core histones and also adding PEG and NaCl (see page 384).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sobczak et al (Eur. J. Biochem. Vol. 175 pp. 379-385 1988) in view of Gaffney et al (US5,710,031 Jan,20, 1998).

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The teachings of Sobczak et al are described previously.

Sobczak et al do not teach 10kb vectors or cloning.

Gaffney et al teach construction of 20-30 bp fragments into vector pVK100 and transferring to *E. coli* for later cloning and testing (see col. 16 lines 14-27).

One of ordinary skill in the art would have been motivated to combine Gaffney et al's recombinant vectors with Sobczak et al's ligation technique in order to promote the intermolecular ligation of fragment to vector. Sobczak et al's technique provides for increased ligation efficiency. It would have been prima facie obvious to apply Sobczak et al's ligation technique employing histones to Gaffney et al's large vectors in order to increase the ligation of large fragments into the pVK100 vector.

Moreover, it was well known and commonly practiced in the art to construct vectors and propagate the vectors in *E.coli* or competent cells for future cloning and analysis.

SUMMARY

9. No claims allowed.

CONCLUSION


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security

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through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Monica Graves for Art Unit 1637 whose telephone number is (703)-306-2938.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.


JEFFREY SIEW
PRIMARY EXAMINER

November 3, 2002